1 of 1

K041066

Summary of Safety and Effectiveness

Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758
512-834-6237

MAR 2 4 2005

Trade Name:
Encore Reverse Shoulder Prosthesis

Common Name:
Cemented semi-constrained total shoulder

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Indications:
The Reverse Shoulder is indicated for use in patients with grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Description:
The Reverse Shoulder Prosthesis is a total shoulder prosthesis designed specifically for use in patients with non-functional rotator cuffs. The articulation of this design is "inverted" compared to traditional total shoulder prosthesis'. Unlike traditional total shoulders, the Reverse Shoulder is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into the humeral stem. The distal surface of the glenoid baseplate is porous coated with an incorporated 6.5 cancellous screw and is intended to be used with 4 peripheral screws (3.5 non-locking and/or 5.0mm locking and non-locking) for additional fixation.

Substantial Equivalence
The Encore Reverse Shoulder is equivalent to the DePuy Delta Shoulder (K0231478).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Ms. Christie Shumaker
Regulatory Affairs Specialist
9800 Metric Blvd
Austin, Texas 78758

Re: K041066
Trade/Device Name: Encore Reverse Shoulder
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/ polymer semi-constrained prosthesis
Regulatory Class: II
Product Code: KWS
Dated: February 28, 2005
Received: March 1, 2005

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number (if known): K041066

Device Name: Encore Reverse Shoulder Prosthesis

Indications for Use:

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The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven Gordon

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041066